

Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations; Alternative Provisions

Response to Comments
Document for the Proposed
Alternative Provisions to
40 CFR Part 194

RESPONSE TO COMMENTS

40 CFR Part 194:

Criteria for the Certification and Re-Certification of the Waste
Isolation Pilot Plant's Compliance with the 40 CFR Part 191
Disposal Regulations

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Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
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INTRODUCTION

The Waste Isolation Pilot Plant (WIPP) is a deep geologic repository in use for the disposal of transuranic radioactive waste. The facility, operated by the Department of Energy (DOE), is subject to compliance with 40 CFR Part 191, *Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes* (hereafter "radioactive waste disposal regulations" or "disposal regulations") promulgated by the U.S. Environmental Protection Agency (EPA or "The Agency"). In 1992 Congress enacted the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA), which called for EPA to issue final radioactive waste disposal regulations, to issue criteria for determining whether the WIPP complies with the radioactive waste disposal regulations and for certifying whether the WIPP facility in fact will comply with the disposal regulations. (WIPP LWA §8, Pub. L. No. 102-599, as amended by Pub. L. No. 104-201).

The compliance criteria, codified at 40 CFR Part 194, explains the basis on which the Agency evaluates whether the DOE's WIPP facility complies and continues to comply with the disposal regulations of 40 CFR Part 191. The WIPP LWA calls for specific criteria in implementing the general disposal regulations at the WIPP facility. This rule – the Alternative Provisions to 40 CFR Part 194 – will revise certain portions of the Compliance Criteria based on EPA's extensive WIPP oversight experience.

BACKGROUND

Radioactive Waste Disposal Regulations: 40 CFR Part 191

EPA has the responsibility of promulgating the Federal environmental standards for spent nuclear fuel, high-level, and transuranic radioactive wastes. Standards for disposal were first promulgated in 1985 and were challenged in the U.S. Court of Appeals. The U.S. Court of Appeals for the First Circuit remanded 40 CFR part 191, subpart B, to the Agency for further consideration. See NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987). Section 8 of the WIPP LWA reinstated the 1985 disposal standards, Subpart B, except those portions that were the subject of the judicial remand. Section 8 of the WIPP LWA also required the Agency to issue final disposal standards, to address the issues that were the subject of the remand. Final amendments were published in the *Federal Register* on December 20, 1993 (58 FR 66397).

WIPP Compliance Criteria: 40 CFR Part 194

As noted, the WIPP LWA requires EPA to promulgate "Compliance Criteria" to implement the disposal regulations specifically for WIPP. See WIPP LWA § 8(c). The Agency published an Advance Notice of Proposed Rulemaking (ANPR) regarding this criteria in the *Federal Register* on February 11, 1993 (58 FR 8029).

The proposed WIPP Compliance Criteria were published in the *Federal Register* on January 30,

1995 (60 FR 5766). The EPA held a public comment period of nearly 150 days. In addition, public hearings were held in Carlsbad, Albuquerque, and Santa Fe, New Mexico in March 1995. See 60 FR 11060.

EPA issued the final WIPP compliance criteria in the *Federal Register* on February 9, 1996. See 61 FR 5224.

Certification of Compliance

The radioactive waste disposal regulations establish general standards that apply to the disposal of spent nuclear fuel, high-level or transuranic radioactive wastes. The regulations require affected disposal systems to analyze their performance over 10,000 years and to predict releases of waste relative to specific containment requirements, to assess potential radiation doses received by individuals and through ground water, and to address assurance requirements intended to provide the confidence needed for long-term compliance with the containment requirements. Under section 8(d)(1) of the WIPP LWA, DOE was required to submit to EPA an application for certification of compliance. Section 8(d)(2) required EPA to determine, by rule, whether DOE's application demonstrated that the WIPP facility would comply with the radioactive waste disposal regulations. These regulations were outlined and explained in the WIPP Compliance Criteria at 40 CFR Part 194. The EPA approved DOE's application and issued a final certification decision in the *Federal Register* on May 18, 1998 (67 FR 27353). This certification permitted the WIPP to begin accepting transuranic waste for disposal, provided that other applicable environmental regulations were met and once a 30-day statutory waiting period had elapsed. EPA based its decision on a thorough review of all the information submitted by DOE, independent technical analyses, and all significant public comments submitted during a 120-day comment period.

Alternative Provisions to 40 CFR Part 194

Based on extensive oversight experience with the WIPP, EPA proposed to revise certain provisions of the Compliance Criteria at 40 CFR Part 194. Specifically, EPA proposed to (1) revise the process for establishing "alternative provisions" in § 194.6; (2) revise the approval process in § 194.8 for waste characterization processes at transuranic waste generator sites for disposal at WIPP; (3) revise the requirements in §§ 194.12 and 194.13 for submission of compliance applications and reference materials; and (4) change the term "process knowledge" to "acceptable knowledge" in § 194.24(c)(3). The revisions will maintain or improve our oversight at WIPP to ensure safe disposal and are intended to ensure that 40 CFR Part 194 remains comprehensive, appropriate, and based upon current knowledge and information. Moreover, these changes will have no effect on the technical approach that EPA employs when conducting independent inspections of the waste characterization capabilities at DOE waste generator sites.

EPA issued the proposed revisions in the *Federal Register* on August 9, 2002. The Agency held a comment period for 120 days. In addition, public hearings were held in Albuquerque and Santa Fe, NM on September 24-25, 2002. See 67 FR 57189 (September 9, 2002; notice of public

hearings). The Agency published newspaper ads in Carlsbad, Albuquerque, and Santa Fe, NM, to announce the dates, times, and locations of the hearings. EPA also posted updated information, fact sheets, and messages regarding the proposed revisions on the WIPP website (<http://www.epa.gov/radiation/wipp>) and on the toll-free WIPP Information Line to facilitate communication with the public.

Approximately 17 sets of comments – seven from the public hearings, four from EDOCKET, and six through e-mail/regular mail – were submitted to EPA regarding the proposed WIPP Compliance Criteria. Comments received on the proposal were categorized according to the following topics, most of which correspond generally to sections of the proposed rule:

- General observations
- EPA’s public hearing process
- Minor alternative provisions
- Proposed inspection regime
- Submission of compliance and reference materials
- “Acceptable Knowledge” definition

While a section of this document is assigned to each topic, the document should be read comprehensively. Some comments presented overlapping issues, while others contain several points, and some comments repeat points that are addressed elsewhere within a particular section or in a wholly different section. While in some instances EPA has cross-referenced related responses, it has not done so in every instance. Thus, the responses to comments set out in this document should not be read in isolation. Rather, the entire document should be considered as a whole, for it collectively reflects EPA’s consideration of significant comments.

This document addresses comments received on the proposed alternative provisions to 40 CFR Part 194 by summarizing the concerns expressed by commenters and presenting the Agency’s response to the comments. The Agency has addressed all significant comments, both written and oral.

Each set of comments submitted to EPA is identified by a numeric/alphabetic code indicating its source. A list of the commenters and their identification is given in Appendix A. Copies of all comments submitted to EPA regarding the proposed rule can be found in Air Docket Number A-98-49 (Categories VI-C and VI-D) and also online at EDOCKET #OAR-2002-0005 (excluding the oral testimony from the public hearings). For more information on docket locations, refer to the *Federal Register* notice for the proposed or final rule. A list of acronyms and the terms they represent are in Appendix B.

ISSUE #1: GENERAL OBSERVATIONS FROM COMMENTERS

- 1-7. We support many aspects of the EPA's proposed changes to 40 CFR Part 194. The changes enhance the flexibility EPA desires in its verification of the transuranic waste sites compliance with the disposal regulations, and should reduce the number of inspections required. (DOE)
- 1-2. As a whole, the revisions suggested are very good. Anything that speeds up the process and makes it more efficient is a good idea. (RW)
- 1-3. Overall, the proposed changes to 40 CFR Part 194 are a step in the right direction and will help the generator sites be able to demonstrate adequate compliance. It will also give the public a better opportunity to provide comment on the potential ruling or potential certification that those sites will endure as opposed to the comment period being prior to the actual inspection; a win-win situation for everyone. (WTS)

Response to Comments 1-1 through 1-3: EPA believes the changes will make the inspections process at DOE waste generator sites more effective and efficient while maintaining safe oversight of disposal operations. And while the amendments improve EPA and public participation processes, EPA is maintaining underlying rigorous waste characterization and other requirements that the WIPP must meet. Furthermore, EPA can more easily make minor revisions in the future to similarly keep pace with technological information and changing practices. These changes will improve implementation of key provisions of the WIPP Compliance Criteria. Also, the amendments allow for electronically submitted information, which can be more easily reviewed and made available to the public.

- 1-4. I am not satisfied that the public is really being heard by either EPA or DOE. The only real way to solve all of these contamination-related concerns is to stop producing nuclear weapons and nuclear waste. That should be the foremost item on EPA's agenda. (RL)

Response to Comment 1-4: At the time Congress withdrew the WIPP site from public domain, Congress delegated certain regulatory responsibilities to EPA (WIPP Land Withdrawal Act, Sections 8 and 9). The issuance of the WIPP Compliance Criteria at 40 CFR 194 is among those responsibilities and the amendment of the Criteria are within EPA's authority. Congress did not delegate to EPA the authority to abandon WIPP or dictate other disposal options because it might affect other defense activities related to radioactive waste or atomic weapons. These considerations are outside the scope of this rulemaking.

- 1-5. We suggest that EPA establish approval, certification procedures, and criteria separate to the 194 rule and have it apply in a more global sense to both high-level waste and transuranic waste for any geologic facility. This is something for EPA to consider in the future. (WTS)

Response to Comment 1-5: The WIPP Land Withdrawal Act authorized EPA to establish compliance criteria only related to the WIPP facility (which EPA outlined in 40 CFR 194). The establishment of criteria for other geologic disposal facilities is outside the scope of this rulemaking.

- 1-6. EPA should incorporate, review, and respond to the concerns raised in EEG's September 2002 entitled "Identification of Issues Relevant to the First Recertification of WIPP," EEG -83. Although these issues are not directly related to the proposed rule, they are nonetheless concerns for the people of New Mexico. (CCNS)
- 1-7. DOE's July 2002 WIPP Performance Management Plan (PMP) documented talks of bringing in waste to the WIPP in an accelerated manner. The document lays out more waste to WIPP in the next five years than what was anticipated. EPA should consider the PMP in the recertification process. (CCNS)

Response to Comments 1-6 and 1-7: Although EPA agrees these issues are important, they are beyond the scope of this proposed rulemaking. These issues will be addressed during the recertification process, as appropriate.

- 1-8. We are concerned about transportation issues (shipment of the waste to the WIPP), especially when driven in through commercial highways. (CCNS)
- 1-9. The transportation of waste to the WIPP is very important and I am aware of two recent accidents. The EPA should also think about spending their money on emergency management training in localities and municipalities. (RL)

Response to Comments 1-8 and 1-9: These comments are beyond the scope of this proposed rulemaking. As stated during the original WIPP Certification, transportation is entirely outside EPA's general authority for regulating radioactive waste. Moreover, in the WIPP Land Withdrawal Act, Congress did not authorize any role for EPA with respect to transportation. Transportation of radioactive waste is regulated by the Nuclear Regulatory Commission, the U.S. Department of Transportation, and the State of New Mexico. All transportation requirements for the WIPP are established and enforced by regulators other than EPA, and the Agency has no regulatory authority to affect transportation routes or requirements.

- 1-10. A company's compliance record, including any instances of non-compliance, fines and penalties, should be used to determine accountability and justification for recertification. (ANON1)
- 1-11. I just can't believe we allow recycling of hazardous waste into fertilizers to place on crops we plan to eat later. (ANON2)
- 1-12. Waste treatment of TiO₂, HF, V₂O₅, CoO₂ water based solution. (SM)

Response to Comments 1-10 through 1-12: These comments fall beyond the scope of this rulemaking.

**ISSUE #2: EPA’S PUBLIC HEARING PROCESS – HELD ON SEPTEMBER 24-25, 2002;
ALBUQUERQUE & SANTA FE, NEW MEXICO**

- 2-1. The timing of the hearings in Albuquerque and Sante Fe precluded most interested people from being able to participate because of the large number of WIPP-related matters that had nearer term deadlines. This is in contrast to the considerable turnout in past EPA rulemaking hearings. For future rulemakings or other public processes, EPA should consult with leading citizen organizations (SRIC, CCNS, NWNM, CARD, etc.) prior to scheduling any hearings. (SRIC, NWNM, CCNS, CARD)

Response to Comment 2-1: EPA understands and appreciates the time and effort required by WIPP stakeholders to meaningfully participate in the Agency’s public hearings and other public fora and processes. Since the Office of Radiation and Indoor Air conducted the first public hearings in New Mexico in 1993, our policy (based on feedback from key WIPP stakeholders, including commenters) has been to schedule public hearings midway through the public comment period associated with the rulemaking action. This timing gives stakeholders time to review the action in order to prepare testimony and submit comments at the public hearing and also allows time after the hearing to submit additional written comments or respond to issues raised in hearing testimony before the close of the public comment period. The public hearing dates selected for the 194 Alternative Provisions Rulemaking were scheduled based on two factors: (1) facility availability in Albuquerque and Santa Fe, and (2) implementing our public hearing time frame consistent with past practice. In the future, EPA will seek greater coordination with stakeholders to facilitate participation in hearings.

**ISSUE #3: SECTION 194.6 – PROPOSED ADDITION OF “MINOR ALTERNATIVE PROVISIONS”
AND CORRESPONDING PUBLIC COMMENT PERIOD**

- 3-1. The EPA proposes to revise Section 194.6 to add a rulemaking process for substituting “minor alternative provisions” of the Compliance Criteria. As a part of this process, the EPA is proposing to reduce the comment period from 120 days to 30 days for minor changes. A 45-day comment period may be more appropriate to make sure that interested parties can submit comments, especially during periods which include major holidays. (EEG)
- 3-2. Although it is good that EPA maintains the public comment period for minor changes, 30 days is not sufficient. 60 days would be more reasonable. (SRIC, CCNS, NWNM, CARD)

Response to Comments 3-1 and 3-2: The proposal at §194.6(b)(2) states that the Agency would give at least 30 days for the public to comment on the minor alternative provisions. That gives the EPA flexibility to provide a longer comment period depending on the complexity or controversy of an issue and public response.

EPA agrees that under certain circumstances a longer comment period is desirable but expects that 30 days will be sufficient for most minor changes, which are expected to be largely administrative and uncontroversial. EPA's final rule specifies a minimum 30-day comment period for minor changes. But, where circumstances warrant, EPA will consider a longer comment period.

- 3-3. The proposed definition of "minor alternative provision" lacks clarity. The following definition should be used: "***Minor alternative provision*** means an alternative provision to these Compliance Criteria that only clarifies an existing regulatory provision, and does not substantively alter the existing regulatory requirements." (SRIC, CCNS)
- 3-4. The "minor alternative provision" definition lacks clarity and requires a more substantial operation definition, or there could be misunderstanding or violations that lead to lawsuits. (NWNM)
- 3-5. The "minor alternative provision" definition in the proposed rule does not have enough criteria or specifics to identify what is minor and what is an alternative provision as the former definition stands. Similar circumstances with the word have been significantly different, so the EPA must be careful in defining the term. However, overall, the revisions in Section 194.6 were a great step in the right direction delineating two portions – one that could be ruled on in a minimal amount of time and another portion that fit all other categories. (WTS)
- 3-6. The definition of "minor alternative provision" is not clear enough. EPA or DOE may define something as minor that the public might consider a moderate or major change. This problem has already occurred several times in the New Mexico RCRA operating Permit Modification process. Language should be included in the Final Rule that limits minor alternative provisions so that they cannot be interpreted to allow substantive changes to current regulations. (CARD, SRIC, CCNS)
- 3-7. I commend EPA for accommodating small changes that are deemed as minor in rules. (RW)

Response to Comments 3-3 through 3-7: We agree with the commenters' suggested changes to the proposed definition of "Minor alternative provision." We have revised the proposed definition to emphasize that a minor alternative provision would **only** clarify an existing regulatory provision and not substantially alter the regulatory requirements. Note that minor provisions,

while subject to a streamlined process, still constitute a full regulatory process with a proposed rule, public comment, and final rule.

- 3-8. The proposed rule change does not clearly stipulate a change between 40 CFR Part 194.6(a) and 194.6(b). If there is a case in which public comment persuades EPA to change its decision on whether an item is “minor” under subsection (b), EPA should issue a notice of final rulemaking rejecting the change and then re-notice it for public comment under 40 CFR 194.6(a). Additionally, EPA should include a provision which states that final determination will depend on public comment. (SRIC, CCNS, NWNM, CARD)

Response to Comment 3-8: EPA believes that the proposed process is adequate to address the commenters’ concerns. In our proposal, at §194.6, we outlined a process that we would follow to propose and finalize minor alternative provisions. As a regulatory agency, EPA must seek public comment on the proposed regulations and fully consider them when issuing a final action. The only difference between the language for alternative provisions under §194.6(a) and that proposed for the minor alternative provisions under §194.6(b) is the length of the comment period and whether public hearings would be required. Depending on the complexity of the issue and the public reaction, the Agency has flexibility and discretion to seek public comments for a period exceeding the minimum required and also to hold public hearings.

ISSUE #4: SECTION 194.8 – PROPOSED INSPECTION REGIME, TIERED APPROVAL PROCESS, AND CORRESPONDING PUBLIC COMMENT PERIOD

- 4-1. EPA should revise the language proposed in Section 194.8(b)(2)(i). The proposed language reads, “*DOE will notify EPA by letter that a transuranic waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs.*” The first sentence of Section 194.8(b)(2)(i) be revised to read, “*DOE will request, by letter, that EPA perform an inspection of the waste characterization processes and programs at a transuranic waste site.*” This is mainly to clarify the rule language and make sure issues such as transportation programs at waste sites (regulated by NRC and DOE, not EPA) and audit approvals are not misrepresented or misinterpreted in any way. (DOE)

Response to Comment 4-1: EPA agrees that it is helpful to clarify the scope of notifications (and EPA inspections) regarding waste characterization programs. We have revised the language in Section 194.8(b)(2)(1) as follows: “DOE will notify EPA by letter that a transuranic waste site is prepared to demonstrate the adequacy of its waste characterization program.” The revised language clarifies that this requirement does not refer to shipping of waste, which is under the jurisdiction of other Federal agencies – the Department of Transportation and the Nuclear Regulatory Commission.

- 4-2. The current process of notice in the Federal Register (publishes site characterization plans

and a 30-day public comment period) provides a better opportunity for public understanding and participation and should be retained. A 30-day public comment period on the proposed “Baseline Compliance Decision,” after EPA has completed its inspection and found the operations to comply with the regulations, would result in additional delay of characterization and waste disposal and unnecessary costs to the government and public. As an alternative, EPA could approve a site to characterize the waste for disposal at the time of EPA’s proposed Baseline Compliance Decision but have a temporary hold where the characterized waste is retained at the site. If EPA decides to go ahead and change the rule as they proposed, the language should specify a short fixed period for accepting comments (no time limit was discussed in the proposed rule), such as 30 days. (DOE)

- 4-3. The proposed text in Section 194.8(b)(2)(iii) does not describe the length of the public comment period on the baseline inspections. EPA should specify “...*at least 30 days to comment.*” We support the proposed change to receiving public comment not only on DOE documentation but also the EPA’s baseline inspection reports and proposed compliance decisions. This proposed change may attract more public comment, especially if the electronic EPA docket initiative is widely utilized. The EPA could also make the results of any Section 194.24 inspections available for comment, just as the Section 194.8 inspection reports and decisions will be made available. (EEG)
- 4-4. 40 CFR Part 194.8(b)(2)(iii) should provide for at least a 60-day public comment period. In the language of the proposed rule, there is no time frame given for the public comment period, although the preamble states that there would be a 30-day comment period. (SRIC)
- 4-5. We support the idea of the public being able to comment on both the DOE documents and on EPA inspections (including baseline inspections if this is approved). However, we object to the 30-day limit on public comment for the reasons previously described. These documents are even more technical than those involved in minor alternative provisions and would require even more time to study. (CARD)
- 4-6. EPA should specify a maximum length for the comment period to prevent unnecessary delays. One of the advantages of the waste-stream-by-waste-stream process was that a site could ship some waste while waiting to get another waste stream approved. If there is no mechanism to prevent these extensions, there could be sites that will simply be bottled up and prevented from shipping anything for indefinite periods of time. (RW)

Response to Comments 4-2 through 4-6: EPA’s proposed rule language did not address the length of the public comment period. However, the preamble to the proposal discussed a 30-day comment period (67 FR 51936). Several comments requested a comment period longer than the 30 days mentioned in the proposed preamble. During this period, the public could review and comment on EPA’s Baseline Compliance Decision, tiering designations, inspection reports, and

relevant DOE technical documents. Some of these documents could be lengthy and highly technical, and EPA agrees that a very short comment period might discourage public comment. Therefore, in the final rule, §194.8(b)(2)(iii) establishes a 45-day comment period on EPA's Baseline Compliance Decision. At our discretion, EPA may extend the comment period on a case-by-case basis. At the end of the comment period, EPA will consider public comments received and issue a final approval decision letter. We plan to post these baseline decisions on EPA's WIPP website, and hard copies of this relevant documentation and other information will be available at our dockets in Washington, DC, and Albuquerque, Carlsbad, and Santa Fe, NM. Interested parties will have the option of submitting comments to the EDOCKET as well. Also note that EPA will docket and post on the WIPP website material relevant to §194.24 inspections for public review without a set comment period. The public may submit comments relating to these inspections and EPA will consider them as appropriate.

EPA does not agree that seeking public comment on the Agency's approval decision may cause excessive delay in waste shipment or incur unreasonable storage costs. In the proposed rule, we have provided that transuranic (TRU) waste sites with approved WC programs could continue to characterize the approved waste streams for WIPP disposal while EPA converts to the new inspection system. Thus, EPA's baseline inspections and final approval at the end of the comment period would have no impact on the disposal schedule for currently approved sites. We believe that the TRU waste sites that have not been approved to date can reasonably adjust their characterization and disposal schedule to incorporate the time necessary for EPA inspection(s), comment period, and a final approval letter and can plan for necessary storage. Approved DOE sites awaiting EPA approval of a "new" waste stream or a waste summary category group can do the same. During the time interval between inspection and approval decision, DOE sites may choose to continue waste characterization activities with an understanding that they may be subject to a follow-up inspection or even disapproval if EPA, upon consideration of public comment, makes such a determination.

- 4-7. EPA should conduct the baseline inspections of transuranic waste sites with current approval when DOE conducts the annual recertification audits. The practice of concurrent audits between EPA and DOE has been beneficial to both parties. (DOE)

Response to Comment 4-7: EPA intends to conduct the baseline inspections at the five approved sites within a reasonable period after the proposed changes take effect. These inspections may or may not coincide with DOE's annual re-certification audits.

EPA agrees that conducting concurrent audits with DOE's Quality Assurance (QA) organization has been beneficial in the past and the proposed rule acknowledged these benefits. The baseline inspections as envisioned would be more comprehensive as EPA inspectors would be establishing tiers for all waste characterization components and potential waste streams, requiring thorough evaluation of processes, procedures, and equipment and discussions with waste characterization (WC) personnel. The process may require longer than the customary 3-day WIPP audits performed by DOE. EPA has the authority to conduct independent inspections at TRU waste

sites and intends to work directly with sites to schedule and conduct these inspections. EPA may invite DOE's QA organization and National TRU Program staff as observers. To make efficient use of resources, when possible we will attempt to schedule concurrent or partially concurrent inspections.

- 4-8. The current inspection requirements and process is excessive. However, as an alternative to the proposed changes outlined in the proposed rule, the baseline inspections could be conducted at each site for each of the three waste summary category groups (or for as many groups as are associated with a site). This is because characterization methods are likely to be applied differently to each group, and the EPA should tailor its approval process to cover these three major physical forms as separate processes. (EEG)

Response to Comment 4-8: EPA agrees that it is important to fully examine how waste characterization is applied, and that there may be meaningful distinctions between the waste summary category groups in this regard. The proposed baseline inspection and tiering process can fully accommodate separate consideration of summary categories if there are significant differences in WC processes. Section IV.B of the preamble to the final rule clarifies the approval process. Briefly, each TRU waste site must demonstrate the adequacy of the site's waste characterization program for approval by characterizing a sufficient number of TRU waste containers belonging to a particular waste stream or the waste summary category. During EPA inspections, we will evaluate the adequacy of the program by assessing whether the site can successfully characterize the waste and meet the WIPP waste acceptance criteria. The baseline approval of TRU WC processes and equipment would depend solely on the site's ability to demonstrate whether the given process, procedure, or equipment can be used to characterize one or several waste streams or waste summary categories. The baseline approval under §194.8 will specify any limitations on the approval. Limitations may relate to waste streams, waste categories, processes, or other factors deemed important by EPA. The baseline approval will also specify, through tiering designations, what level of EPA review and approval is necessary for future changes or expansions to the WC program at a site (including, for example, expanding the program to encompass new waste streams). This approach allows for limits on waste stream characterization where meaningful, but provide flexibility for EPA to establish limits on other criteria which may be more technically important at a given site.

- 4-9. A maximum time period should be specified for which the site baseline inspection is valid, or a maximum time between inspection conducted under Section 194.24. A two to three year maximum may be appropriate. (EEG)
- 4-10. We object to the open-ended nature of the proposed 194.8(b). The WIPP site is supposed to operate for 35 years and safely contain radionuclides for 10,000 years – a one-time approval of waste characterization practices would be unsafe and irresponsible. Thus, any baseline decision should be limited by rule to no more than a specified number of years, preferably no more than three years. Thus, the baseline would need to be reviewed and updated at appropriate intervals. (SRIC)

4-11. We object to the proposed changes in Section 194.8, mainly with the provision that states waste generator sites will require only one 194.8 approval for all waste streams indefinitely. This is entirely unacceptable, as this reduction in required approvals is potentially reducing oversight and enforcement of DOE sites. (NWNM, CCNS, CARD)

Response to Comments 4-9 through 4-11: The comments indicate that EPA did not make sufficiently clear the nature and purpose of the proposed regulatory changes. EPA does not believe that the proposed changes would reduce either the number of inspections nor the level of oversight and enforcement at DOE sites. The changes will modify the EPA inspection and approval procedures, but will not necessarily affect the frequency or number of times a site will be inspected. Under 40 CFR 194, EPA may inspect DOE TRU sites' waste characterization activities using the inspection authority under §194.8 and §194.24. The new process provides that the individual waste generator sites will need only one §194.8 approval from EPA to conduct WC activities. However, this single §194.8 approval will specify any limitations on the approval that will necessitate additional inspections by EPA. Any such additional inspections will be conducted under authority of §194.24(h), not under §194.8. Limitations on the initial §194.8 approval may relate to waste streams, waste categories, processes, or other factors deemed important by EPA and will specify what WC program expansions or changes must undergo further EPA inspection or approval under §194.24. For Tier 1 activities (which could include, for example, the use of a new waste characterization process not previously applied to any waste streams at a site), DOE must notify and obtain EPA approval in advance of sending waste to WIPP that was characterized with the new method. The EPA would expect to conduct on-site inspections to evaluate many Tier 1 activities. Furthermore, EPA's proposed Baseline Compliance Decision, including any proposed limitations, will be subject to public comment.

The Agency does not agree that it is necessary to require a re-evaluation of EPA's site-specific Baseline Compliance Decisions at a set interval. As discussed in the preamble to the proposed rule and reiterated above, EPA will conduct additional site inspections under §194.24 to verify continued compliance with the baseline approval in accordance with the tiering designations or as otherwise deemed necessary. Since 1998, EPA has inspected WC programs at TRU waste sites under §194.24 on an approximately annual basis; generally the Agency has conducted these inspections to coincide with DOE's annual recertification audits. We are likely to maintain at least the same frequency for future continued compliance inspections under §194.24 and may inspect more frequently as Tier 1 activities warrant (i.e., if DOE undertakes specified expansions or changes to the approved WC program). A reduced frequency of inspections might also be warranted if, for example, a site has no characterization activity over a period of time. The final rule offers flexibility in scheduling inspections as necessary while not diminishing in any way the effectiveness of our inspections program.

Because EPA expects to continue to inspect sites regularly, we do not believe it is necessary to specify an expiration date for the baseline compliance approval. Through ongoing compliance inspections (prompted by tiered activities/changes at the site or at EPA's own discretion under

§194.24), EPA will validate that approved processes and equipment continue to be adequately implemented. The baseline approval will remain valid so long as the site continues to demonstrate appropriate use of approved processes.

EPA expects that the baseline compliance inspections and approval process will be more wide-ranging than the current inspection regime since it will not be limited by waste stream designations and will explicitly address future expansions of the characterization program. The first approvals conducted under the new process are likely to be highly detailed and very intensive, since EPA will need to work with DOE and stakeholders to ensure that the full range of waste characterization activities is identified and placed in appropriate reporting/approval tiers. The final rule provides important flexibility to ensure that EPA can effectively implement – and that the public can fully understand and participate in – the new process. The final rule does not establish a time period within which EPA must “convert” sites to the new inspections and approval process. DOE sites with approved waste characterization programs will be allowed to continue operations under the existing inspection and approval process based on waste streams; the waste stream system, while less flexible than the newly revised process, remains rigorous and can continue to provide effective oversight during the transition period. We expect to review approved programs and issue new baseline approval decisions for those sites within approximately two years. However, the Agency retains the discretion to take longer (if warranted) by the complexity of technical issues or the scope of more comprehensive inspections. Similarly, we decline to limit the length of the comment period on proposed baseline approval decisions. We believe that limiting the available comment period would be counterproductive for both EPA and the public in adjusting to the new process, and could constrain discussion if unanticipated or especially complex issues arise.

The results of all EPA site inspections, under §194.8 and §194.24, will be made available to the public in EPA’s dockets, WIPP website, and other means. If, at any time, we determine that the system of controls at a site is not adequate to characterize certain waste streams, EPA retains authority to direct that the site may not dispose of material from those waste streams or processes at the WIPP until the Agency’s findings have been adequately resolved. We believe that the changes will result in equivalent or improved oversight of waste characterization activities.

- 4-12. We also have concerns over the EPA’s proposed tiering system for baseline approval; mainly, that DOE can implement changes under this tiering system prior to reporting these changes to EPA. This is analogous to DOE’s submittal of WIPP Hazardous Waste Facility Permit Modification Requests, which have been submitted at minor class levels, only to be rejected and require re-submittal as a major modification. Given this history, the EPA should require DOE to seek a preliminary concurrence for tier selection, prior to formal submittal. The approval of Tier 2 changes could be a less cumbersome process than those of Tier 1, and would not need a public comment process. Also, it appears that Tier 2 changes agreed upon between the EPA and the DOE may never be publicly disclosed. The EEG suggests that a notification of Tier 2 changes be made, but not require a public comment period. (EEG)

Response to Comment 4-12: EPA does not believe that the proposed tiering system is analogous to DOE's submittal of WIPP Hazardous Waste Permit Modification Requests. For example, when submitting a WIPP permit modification to the State of New Mexico (i.e., NMED) DOE interprets NMED's classification levels for permit modification. Sometimes NMED has rejected class designations as construed by DOE. Under today's rule, EPA's baseline approval will specify any limitations on the approval. It will also specify what subsequent WC program changes or expansion must undergo further EPA inspection or approval under §194.24 by assigning tiering designations to these activities. EPA will assign the tiering designations. This eliminates the possibility of misinterpretation on DOE's part and the possibility of EPA not agreeing with DOE's selection of a tier. In addition, the public will have the opportunity to comment on which activities should be assigned to each tier.

EPA would like to further clarify the details of the tiers. Tier 1 waste characterization activities at a site will have more stringent reporting requirements. These activities will require notification by DOE and approval by EPA prior to shipment of waste to the WIPP. We expect to conduct site inspections as part of our decision-making process for many Tier 1 activities. Tier 2 activities will have more moderate reporting requirements and EPA may approve changes to certain activities without a follow-up inspection (i.e., desktop review and approval of certain technical documents). These activities will require a notification by DOE to EPA on the specific changes; however, waste can be shipped to the WIPP without prior Agency approval. For Tier 2 notifications, EPA will review the documentation provided by DOE and reply only if additional information or analysis is needed. Other changes (i.e., if no tier is specified) will be captured in DOE's annual change reports or continuing compliance inspections under § 194.24.

DOE will report any changes in equipment, processes, or personnel, based on their tier level, and certain changes must be reported to EPA before the sites are allowed to ship waste using the waste characterization activities in question. EPA will then decide whether or not a follow-up inspection is necessary to confirm and verify the adequacy of any changes to the site's waste characterization program. EPA may also conduct unannounced site inspections of a tiered activity if EPA determines a need based on the available information. Below are examples of how the tiers may be assigned:

- In its baseline inspection by EPA, a site ("Site 1" in this example) demonstrates that it can quantify 10 WIPP-tracked radionuclides only in homogeneous organic solids using a particular piece of radioassay equipment ("Equipment A" in this example). The baseline approval for Site 1 is issued and the non-destructive assay (NDA) equipment is approved with the limitation that it may be used to characterize only homogeneous solids. As part of the baseline approval, the change to use Equipment A on a new waste stream is designated a Tier 1 change. Therefore, if Site 1 would like to use Equipment A to characterize inorganic sludge then an additional EPA approval will be necessary.
- Site 1 would now like to use a different piece of equipment ("Equipment B" in this example) to characterize the same waste stream that they are already approved for (in this

case, homogeneous solids). Equipment B is nearly identical to Equipment A in specifications and operating controls. As part of the baseline approval, EPA specifies that using equivalent equipment to characterize an approved waste stream is a Tier 2 change. Therefore, Site 1 notifies EPA of its plans, provides documentation to EPA that Equipment A and B are equivalent, and can install and operate the new equipment without prior approval by the Agency.

For both Tier 1 and 2 changes, DOE must submit to EPA information discussing the relevant program changes for our evaluation. Prior to approval, Tier 1 changes may require an inspection to obtain objective evidence demonstrating a site's WC program adequacy and WC data showing compliance with the WIPP compliance criteria at 40 CFR 194. EPA will docket and post information from these §194.24 inspections on the WIPP website for public review. Generally, Tier 2 changes would not require inspections, provided that EPA is satisfied with the information submitted by DOE regarding the changes. EPA's approval letter discussing Tier 1 or Tier 2 changes would explain how the available information was sufficient to justify a decision, or what additional information was collected during an inspection, if one was conducted. Also, EPA will docket and post on the WIPP website the Tier 2 approval letter and DOE submission for public review.

Once the Baseline Compliance Decision has been made and tiers have been assigned at the sites, the EPA may decide to revise the tiering designations, based on a variety of factors. Some sites may have a harder time converting to the more robust inspections regime, and certain aspects of their WC program that were strong in the past may need more intense scrutiny. Conversely, certain sites will undoubtedly improve their overall performance as they become accustomed to the new system, and certain aspects of their WC program will subsequently require less attention. The decision to revise tiers at a site will be made through continued compliance inspections under the authority of § 194.24(h), as previously discussed. The Agency will announce the proposed tier changes and the reasoning behind them in the site's inspection report, which will be posted on the WIPP website and docketed in accordance with § 194.67. If the tier change is an elevation in stringency from Tier 2 to Tier 1 (i.e., additional DOE reporting requirements for that particular waste characterization component or activity), the change will be effective immediately and the site will be expected to operate under the more stringent requirements without delay. If, however, the change is a "downgrade" in stringency from Tier 1 to Tier 2, the inspection report will solicit comments from the public, for a minimum of 30 days, to let them raise any concerns they might have. The site will continue to operate under the more stringent tier designation until public comment can be considered.

- 4-13. EPA's proposed change to allow the Central Characterization Project (CCP) to be approved once for all waste streams is equally unacceptable. This opens the door for a number of issues that parallel the problems that occurred with INEEL in July 2001. (NWNM, CARD)

Response to Comment 4-13: EPA does not approve DOE's CCP activity at only one site such

that CCP's waste characterization staff can go to other DOE sites to characterize TRU waste. To date, EPA has inspected and approved CCP WC activities at each of the three sites where it is currently being used and approved only one waste stream at each (TRU debris waste) for the disposal at WIPP. As stated in the preamble to the proposed rule, under the new provisions, EPA approval under §194.8(b) will still be required for CCP operations at each site (67 FR 51937/3). However, to clarify our intent, we emphasize that once we have evaluated the CCP at a site, we will determine whether the CCP may be approved to characterize all waste streams at that site only. Under the new provisions, EPA may impose waste stream or other limitations on its approval when appropriate.

- 4-14. EPA should also take into account the events at the Savannah River Site (SRS). The EPA approved an SRS program for characterization of a single debris waste stream in April 2001. The December 2002 audit was intended by the DOE to expand this approval to other debris waste streams; however, the EPA's inspection report found that *"During the inspection, EPA determined that SRS did not demonstrate that the characterization systems inspected were adequate to be extended to all retrievably stored, contact-handled debris waste."* Thus, the requirements for baseline inspections should ensure that there is some surety that additional waste streams to those actually audited will be able to be characterized in a way that maintains the quality of characterization established by the baseline inspection. (EEG)

Response to Comment 4-14: The information from the SRS inspection cited by the commenter is accurate. The baseline approval and tiering process that the Agency is finalizing today would establish whether a site can adequately characterize additional waste streams with physical and radiological characteristics similar to those for an approved waste stream. For example, to minimize the likelihood that a site might interpret the EPA approval of an individual waste stream to apply to other wastes belonging to the same waste summary category group, EPA inspectors will evaluate objective evidence obtained at the site and specify, through tiering designations, whether the application of approved WC techniques to other waste streams would require additional inspection and approval by EPA. If additional approval is required, once a site collects sufficient data to demonstrate its ability to characterize the waste in question, it will notify EPA and submit relevant information. EPA will review information and may perform an inspection to verify the site's capability. Only after making the adequacy determination will EPA approve waste for disposal at WIPP. As always, if a problem is discovered, EPA retains its discretion to conduct additional inspections or restrict waste shipments.

- 4-15. All existing sites have had some difficulty in fully complying with EPA's existing requirements (INEEL in 2001, LANL shipment delays, etc). The proposed rule does not describe these situations, does not show how the proposed rule will make improvements to EPA inspection procedures, nor how the public participation process will be improved. Thus, EPA has not provided an adequate rationale for the revised procedures. (SRIC)

Response to Comment 4-15: EPA referred to the INEEL 2001 incident in the Background

Information Document (BID) submitted with the proposed rule on August 9, 2002. Briefly, at INEEL, the site erroneously concluded that a new WC system that was put to use for a period of time was similar to the one approved by EPA. INEEL's QA organization noted this mistake and informed the DOE QA organization and EPA in turn. EPA immediately ordered INEEL to suspend all TRU waste characterization activities at the site, stopped the waste truckload en route to WIPP for disposal, and asked that WIPP not process INEEL TRU waste containers for placement in the repository. EPA inspected INEEL's new WC system to determine whether INEEL was characterizing the TRU debris waste appropriately and TRU waste containers analyzed using the new system complied with the radioactivity limits. Under today's rule, we will assign tiering designations to different WC processes and equipment at each site. Major WC processes and equipment (such as radioassay systems) will be assigned Tier 1, so that incidents like INEEL (2001) are avoided.

As discussed in the proposed rule (67 FR 51930), the Agency aims to improve public participation by providing an opportunity to comment on EPA inspection reports and proposed approval decision in addition to DOE program documents and other information. Thus, the public would be well informed about the inspection that was performed, which decisions are proposed and why, and can provide comments related to the approval and tiering process.

4-16. DOE has not even reached much of the very old waste streams that may be more difficult to characterize adequately. Problems will be exacerbated if remote-handled (RH) waste is added in for characterization. There are too many unknowns involved with future and possibly older waste streams to allow blanket approval for a program and processes that are in place now. (CARD)

Response to Comment 4-16: EPA agrees that DOE has not begun characterizing many of the older or more complex waste streams, including RH waste, that could pose particular technical challenges. Under the inspection process we are finalizing today, DOE sites will still have to demonstrate and obtain EPA approval of their ability to characterize "difficult-to-characterize" TRU wastes. EPA can specify limitations on the baseline compliance approval for a site. Limitations may relate to waste streams, waste categories, processes, or other factors deemed important by EPA. Limitations on the initial §194.8 approval will specify what WC program changes or expansion must undergo further EPA inspection or approval under §194.24 by assigning tiering designations to these activities. Limitations on waste stream approvals are likely to be meaningful in relation to especially complex or unique waste streams or when limited acceptable knowledge is not available. Expansion of the WC program beyond the limitations would be subject to the assigned tiering designations (which would be open to public comment at the time of the Baseline Compliance Decision). Given the complexities of RH waste characterization and the fact that innovative techniques must be tailored to assess these specialized waste streams, we would expect that any program expansion to RH waste would be designated a Tier 1 activity requiring advance notification and approval by EPA and would include an on-site inspection (unless the site could demonstrate adequacy for the particular RH waste stream at the time of the Baseline Compliance Decision).

- 4-17. Public involvement in the approval of waste characterization programs has been inadequate. One significant source of the problem is related to the fact the EPA issued 40 CFR 194.8 as part of the WIPP Certification Decision on May 18, 1998, so there was no opportunity for public comment on a proposed provision. (SRIC)
- 4-18. We acknowledge that, for several reasons, very few people or groups actually comment now on EPA inspections. Members of the public do not see the notices that announce these inspections. Perhaps notice could be given, at least here in New Mexico and around the involved sites in other ways such as newspaper ads (not just legal notices) and radio announcements, and EPA could seek to expand a list of interested people and groups who would be informed directly. (CARD)

Response to Comments 4-17 and 4-18: EPA fully discussed both the reasons for requiring site-specific waste characterization determinations and a proposed mechanism for carrying out these requirements. See the proposed WIPP Certification at CFR 58814/2 - 58815/1.

Over the past 4 years, EPA has made every effort to inform public of EPA inspections when necessary by issuing a *Federal Register* notice and posting updates on the EPA's WIPP website. DOE documents and other material related to these inspections has also been docketed at each of our docket locations. However, we recognize that the highly technical nature of the documents available for comment may have discouraged public participation. In recognition of this, the changes to the site approval process include significant changes to the public comment process. The changes allow for comment not only on DOE's technical documents, but also on EPA's proposed decision on site approval. The public will also be able to comment directly on the proposed tiering designations (and associated level of EPA review and approval) for subsequent changes or expansions of the WC program at a given site. A minimum 45-day comment period will be opened for the proposed Baseline Compliance Decisions at each site.

EPA acknowledges that the *Federal Register* is not the only effective tool for providing information to the public. Under these revisions, EPA will issue a *Federal Register* notice for the initial Baseline Compliance Decision at each site. EPA also expects to use e-mail, web updates, and other more user-friendly communication tools to notify stakeholders of the occurrence and results of baseline approvals and subsequent ongoing inspections.

- 4-19. EPA's justification that the existing requirement should be changed because DOE's program "*will overwhelm our resources.*" is not appropriate. The changes should be justified on a technical basis. (EEG, SRIC, CARD)

Response to Comment 4-19: We believe that the proposed changes are fully justifiable on a technical basis. While resource consideration is a valid factor, the discussion of resources in the preamble to the proposal may have been misleading in regard to its relative importance. The revised process provides equivalent or improved oversight, more control over schedule, better

prioritization of technical issues and distinctions, and flexibility to address relative levels of experience or expertise at various DOE sites. (See also comments 4-10, 4-12, 4-13.)

- 4-20. The reference in the proposed Section 194.8(b)(3)(i) to Section 194.4(b)(1) and (2) could change the relationship between the processes of certification and recertification of the WIPP and the processes of determining baseline and continued compliance of waste generator sites. The provisions of Section 194.4 are specific to the WIPP certification and are not appropriate responses to noncompliance at a waste generator site.

The reference to Section 194.4 should be removed. The new rule should contain its own discussion of suspension, modification, and revocation of a waste site's Baseline Compliance Decision, because the provisions of Section 194.4 are specific to responses to noncompliance at a WIPP site.

The provisions dealing with waste generator sites should explicitly state that the EPA's decisions regarding waste generator sites have no bearing on WIPP certification or recertification. Inspections of waste generator sites and the subsequent findings are irrelevant to the long-term performance of the WIPP repository. Suspending, revoking, or modifying the WIPP Certification due to problems at a waste generator site would be arbitrary and capricious because the EPA has neither explained how nor justified why noncompliance at a waste generator site could invalidate the certified performance of the WIPP. (JHA)

- 4-21. The language in Section 194.8(b)(3) suggests that Section 194.4(b) be utilized as a mechanism for determining whether or not waste generator sites are in compliance, and what actions to take if they are not. The proposed language seems to indicate that EPA could jeopardize the WIPP facility certification. If a single generator site is problematic, all the other generator sites should not have to pay a penalty because one facility is not in compliance. EPA has neither explained how nor justified why noncompliance at a single site could invalidate the certified performance of the WIPP. (WTS)

- 4-22. We strongly disagree with the oral testimony provided on behalf of John Hart Associates and Westinghouse TRU Solutions at the September 24-25 hearings regarding proposed 40 CFR Part 194.8(b)(3)(i). Those contractors expressed concerns that waste characterization programs and processes that are not adequately implemented at a generator site could result in modification, suspension, or revocation of the WIPP Certification under 40 CFR 194.4(b)(1) and (2). Those contractors do not believe that it is appropriate to tie certification requirements for WIPP disposal with waste characterization problems at individual sites. EPA should be clearly authorized to not only suspend shipments from the generator sites, as provided in the proposed rule, but to also take action regarding the WIPP Certification, including suspending operations at WIPP. Thus, we support the proposed 40 CFR 194.8(3)(i) and encourage EPA to preserve it in the final rule and to not modify or remove it as was suggested by the two contractors' oral

comments. (SRIC)

Response to Comments 4-20 through 4-22: Proposed section 194.8(b)(4)(i) provides that EPA may suspend shipments of TRU waste from an approved TRU waste site if EPA subsequently determines that waste characterization programs or processes are not adequately established or implemented. In addition, if necessary, EPA may take action under section 194.4(b)(1) or (2). Section 194.4(b)(1) provides that EPA may suspend, modify, or revoke the certification of the WIPP. Suspension may be at the discretion of EPA; modification or revocation will be conducted by rule pursuant to 5 U.S.C. § 553. Section 194.(b)(3)(i) provides that EPA may request that DOE provide information to enable EPA to determine whether suspension, modification, or revocation of the certification is warranted. DOE's inability to properly establish, maintain, or implement adequate waste characterization activities at a waste generator site could lead to circumstances that necessitate consideration of suspension, modification, or revocation of the WIPP certification. Poorly and/or inadequately characterized waste when emplaced in the repository could be relevant to determining the long-term performance of the WIPP. Therefore, EPA disagrees that the provisions of section 194.4(b) are "specific" only to the WIPP facility, and can never be relevant to activities at a waste generator site.

4-23. If EPA is going to revisit all of the waste generator sites (including those already-approved), does that imply that EPA hasn't been doing their job when they authorized the sites to begin shipment? Doesn't this mean you're putting these sites in a position of essentially having to start all over again? The rationale for this is not clear. This could imply that the initial authorizations up to this point were not particularly well done in the first place, which I'm sure is not the case. Is there some intermediate step that could be done for sites where EPA has already authorized shipment? (RW)

Response to Comment 4-23: The purpose of this re-visiting/re-approving of already approved sites (LANL, RFETS, INEEL, Hanford, and SRS) is to provide an opportunity both to seek further information in support of our tiering decision and to allow for public comment on our proposed tiering designations for those sites. While we have a great deal of experience at those sites, we will nevertheless be performing a baseline §194.8 inspection to gather additional information to inform our tiering assignment decision. Sites that have already been approved can continue to ship waste until and while the new Baseline Compliance Decisions is being made. We expect the baseline decision would incorporate previously approved waste streams and WC processes, provided the baseline inspections show they continue to be adequately executed.

4-24. Public safety is not the major concern of the EPA regarding WIPP. EPA really needs to get "tough" with DOE and tell them they need to inform everyone openly of what is really going on in their waste characterization activities, and that EPA should not be making regulations more "flexible" as the proposed changes claim. (RL)

Response to Comment 4-24: In the preamble of this final rule, EPA has described aspects of this rule as "flexible." EPA does not imply that this change will diminish in any way the level or

efficacy of our congressionally mandated oversight of the DOE waste characterization programs at sites. Instead, it is a recognition by experienced EPA inspectors of the differences in waste characterization processes at each site and the need to have the flexibility to inspect each site effectively. EPA is committed (both in the past and as a result of this rule) to oversight of the items and activities that are important to the containment of TRU waste at the WIPP and the protection of public health and the environment.

ISSUE #5: SECTIONS 194.12 AND 194.13 – SUBMISSION OF COMPLIANCE APPLICATIONS AND REFERENCE MATERIALS

- 5-1. We endorse the reduction in the number of copies of compliance applications and reference materials as proposed in the changes to Section 194.12 and Section 194.13. This change will reduce costs and improve the efficiency of these activities. (DOE)
- 5-2. We agree that the reduction of paper copies is beneficial, especially when electronic copies are more easily disseminated. However, the EPA needs to specify where the five paper copies are destined to ensure proper availability to all concerned parties. (EEG)
- 5-3. We do not oppose the reduction in the number of paper copies of compliance applications and reference materials so long as each of the New Mexico dockets receives a paper copies of these materials and ready access to an alternative format. EPA should state that the intent is to provide paper copies to each New Mexico docket. The rule should require DOE to make copies of compliance applications and reference materials widely available to the public in either written or electronic form. (SRIC, CCNS)
- 5-4. Although digital formats and the internet can make access to and commenting on compliance applications and other documents much easier for some, many people still have not fully made the change from print to digital media, especially minority members of the public. With ten required copies of applications and reference materials, there is at least more access to these documents even though ten might actually not be enough. CARD would hope that there would be copies available in at least Santa Fe and Albuquerque, New Mexico. Has EPA received requests from other states or localities for hard copies of materials? Limiting the public's access to printed media to only four public dockets seems extremely restrictive and almost guaranteed to lessen public participation. (CARD)

Response to Comments 5-1 through 5-4: EPA believes that taking advantage of electronic and digital media can improve public access and facilitate public review of information, as well as being cost effective and environmentally responsible. However, the Agency acknowledges that there is not universal availability or understanding of computers. Furthermore, EPA is committed to maintaining the public dockets in New Mexico, as described in the WIPP Compliance Criteria at §194.67. Thus, EPA's documentation and outreach include both paper and electronic media

(documents will be available online as well as in hard copy form). In the final rule, EPA will specify that the five paper copies are intended for the official docket in Washington, DC, and for the information dockets in New Mexico. The Agency has not received many requests from other states or localities for hard copies of documents; however, EPA has always sent materials to interested parties upon request.

- 5-5. We are in favor of the proposed changes outlined in Sections 194.12 and 194.13. We recommend, however, that the exact number and specification of applications and reference materials be left open for negotiation between DOE and EPA and not specified in the regulations or as an alternative specified in guidance documentation. (WTS)

Response to Comment 5-5: EPA is requiring DOE to submit five paper copies of the recertification application and related materials. These copies will be placed in the public dockets to meet our obligations to outlined in §194.67. Documents will also be obtainable electronically, as well as available upon request. EPA and DOE may also negotiate submission of additional copies of these materials as needed.

ISSUE #6: SECTIONS 194.2 AND 194.24 – DEFINING “ACCEPTABLE KNOWLEDGE” AND REPLACING “PROCESS KNOWLEDGE” WITH THE NEW AK DEFINITION

- 6-1. We endorse the use of “acceptable knowledge” in place of “process knowledge” as proposed in the change to Section 194.24(c)(3). (DOE, RW)
- 6-2. We support the EPA’s decision to replace the term “process knowledge” with the term “acceptable knowledge.” We note that the definition of “process knowledge” as described left great latitude in applying the definition. (EEG)
- 6-3. We do not object to the change from “process knowledge” to “acceptable knowledge,” nor to the definition of the latter term. (SRIC, CCNS, CARD)

Response to Comments 6-1 through 6-3: §194.2 will now define “acceptable knowledge” as *“...any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste, conducted prior to or separate from the waste certification process authorized by EPA’s Certification Decision, to show compliance with Condition 3 of the certification decision...”*

APPENDIX A:

LIST OF COMMENTERS

Public Hearings on the proposed alternative provisions to 40 CFR 194 were conducted in two New Mexico sites. The dates of the proceedings were as follows: Albuquerque, September 24, 2002; Santa Fe, September 25, 2002. The following is a list of those individuals who testified including their place of residence, title and affiliation, if applicable. An asterisk (*) is used to denote that the individual submitted written documentation to complement his/her oral testimony.

Albuquerque Hearing

<u>Comment ID</u>	<u>Name</u>
JHA	*Sharla Bertram, Contractor, John Hart & Associates
SRIC	*Don Hancock, Southwest Research and Information Center
RW	Ruth Weiner

Santa Fe Hearing

<u>Comment ID</u>	<u>Name</u>
CCNS	*Joni Arends, Concerned Citizens for Nuclear Safety
CARD	*Deborah Reade, Citizens for Alternatives to Radioactive Dumping
WTS	*Steve Casey, Westinghouse TRU Solutions
RL	Rick Lass, Green Party (New Mexico State Representative)

Electronic (using the EPA's EDOCKET system) comments on the proposed rule were submitted to EDOCKET #OAR-2002-0005. The following is a list of commentors and where appropriate, the organizations they represent.

EDOCKET Comments

<u>Comment ID</u>	<u>Name</u>
ANON1	Anonymous Commenter
ANON2	Anonymous Commenter
SM	SPECMAT

Written comments received through e-mail or regular mail on the proposed rule were submitted to EPA's Air Docket (Attn: EDOCKET #OAR-2002-0005 or A-98-49). The following is a list of commentors, state of residence (if known), and where appropriate, the organizations they represent.

Mailed Comments

<u>Comment ID</u>	<u>Name</u>
DOE	Patrice M. Bubar, Associate Deputy Assistant for Integration and Disposition, Office of Environmental Management, Department of Energy
EEG	Matthew K. Silva, Director, Environmental Evaluation Group
SRIC	Don Hancock, Southwest Research and Information Center
CCNS	Joni Arends, Concerned Citizens for Nuclear Safety
NWNM	Geoff Petrie, Nuclear Watch of New Mexico
CARD	Deborah Reade, Research Director, Citizens for Alternatives to Radioactive Dumping

APPENDIX B:

LIST OF ACRONYMS

AK - Acceptable knowledge
BID - Background information document
CAR - Corrective Action Required
CARD - Compliance Application Review Document
CBFO - Carlsbad Field Office
CCA - Compliance Certification Application
CFR - Code of Federal Regulations
CH - Contact handled
DOE - Department of Energy
EEG - Environmental Evaluation Group
EPA - Environmental Protection Agency
INEEL - Idaho National Energy and Engineering Laboratory
LANL - Los Alamos National Laboratory
NDA - Nondestructive Assay
NPRM - Notice of Proposed Rulemaking
NTS - Nevada Test Site
NQA - Nuclear Quality Assurance
PK - Process knowledge
QA - Quality assurance
RC - Radiochemistry
RCRA - Resource Conservation Recovery Act
RFETS - Rocky Flats Environmental Technology Site
RTR - Real-time radiography
SRS - Savannah River Site
TRU - Transuranic
VE - Visual inspection
WAC - Waste Acceptance Criteria
WAP - Waste Acceptance plan
WC - Waste characterization
WIPP - Waste Isolation Pilot Plant
WIPP LWA - WIPP Land Withdrawal Act
WWIS - WIPP Waste Information System